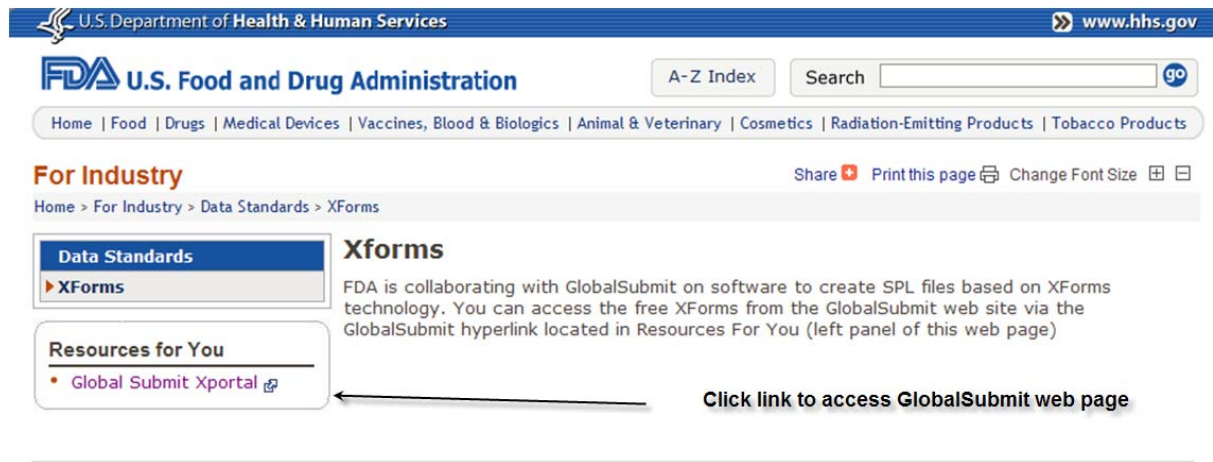


Downloading and Opening SPL Xforms

Basic instructions for installing Mozzie
Add-on & downloading SPL Xforms
Version 1.0

Installing Mozzie Add-on



- The Mozzie Add-on **MUST** be installed **prior** to using SPL Xforms
- Use GlobalSubmit web page accessible via:
<http://www.fda.gov/ForIndustry/DataStandards/XForms/default.htm>
- Navigate to GlobalSubmit web page using link in “Resources for You” panel

Downloading Mozzie Add-on

Browser Requirements

To use XForms, you must have XForm support installed in your browser.

Internet Explorer

Use [IE 6.0](#) or higher (IE7 recommended) with [MozzIE 1.8 Add-on](#). MozzIE is required to support XForms in the IE browser.

Click here if you are using Internet Explorer

Firefox

Use Firefox 2.0.0.13 and install the [Mozilla XForms 0.8.5 Add-on](#).

After installing the [Mozilla XForms 0.8.5 Add-on](#), go to menu, Tools > Options > Security and check 'Allow XForms to access other domains.' Click on 'Allowed Sites' and add GlobalSubmit.com to the list with the 'Load' and 'Send' checkboxes checked.

Click here if you are using Firefox

- In the middle panel of the GlobalSubmit web page, click the link for:
 - the link to the add-on for Internet Explorer or
 - the link to the add-on for Firefox

Downloading Mozzie Add-on cont...

MozzIE is a plug-in for Microsoft Internet Explorer that allows the display of XHTML + XForms using the Mozilla Gecko Rendering Engine

[View all files >](#)

Browse Files for MozzIE

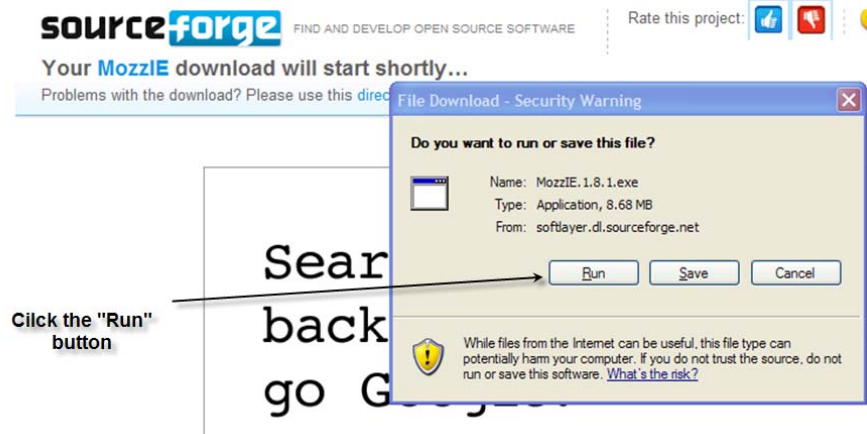
File/Folder Name	Platform	Size	Date ↓	Downloads	Notes/Subscribe
Subdirectory (view all files)					
MozzIE 1.8		19.3 MB	2009-06-25	7,557	
Release 1.8.1		9.1 MB	2009-06-25	2,350	Click here
1.8.0		10.2 MB	2007-09-17	5,207	

- Click the link to the Mozzie add-on

Browse Files for MozzIE

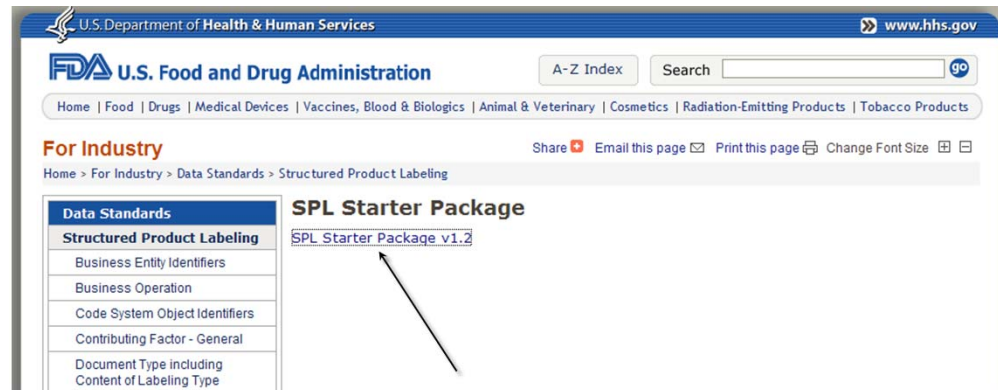
File/Folder Name	Platform	Size	Date ↓	Downloads	Notes/Subscribe
Subdirectory (view all files)					
MozzIE 1.8		19.3 MB	2009-06-25	7,557	
Release 1.8.1		9.1 MB	2009-06-25	2,350	
MozzIE.1.8.1.exe		9.1 MB	2009-06-25	2,350	Click here
1.8.0		10.2 MB	2007-09-17	5,207	

- Click the link to the executable file download



- Select “Run” to begin download
- After downloading add-on, reboot (turn-off) computer
- Restart computer

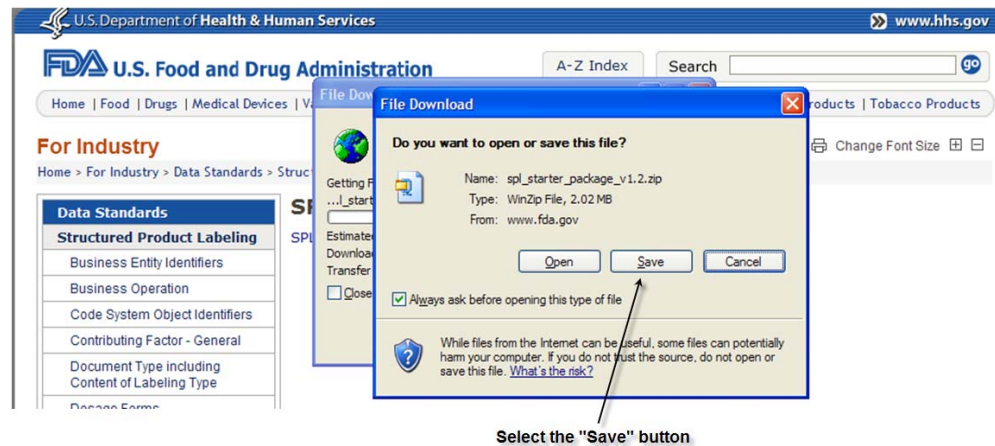
Locate SPL Starter Package



Click the hyperlink

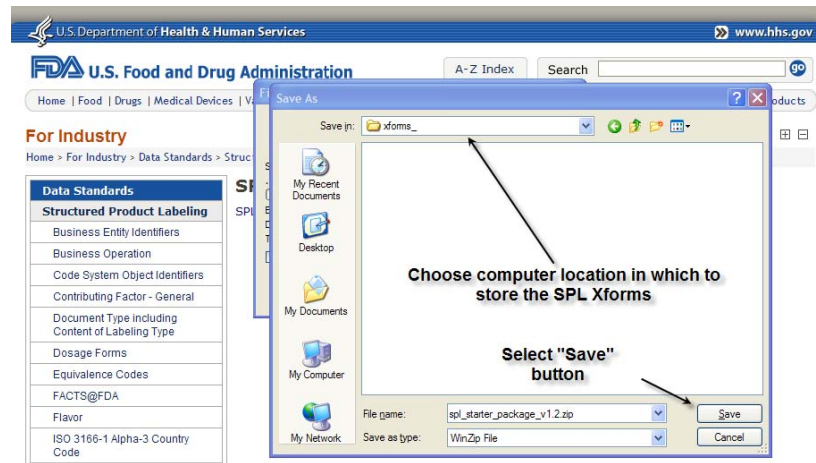
- Link to SPL Starter Package:
- <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm>

Download SPL Starter Package



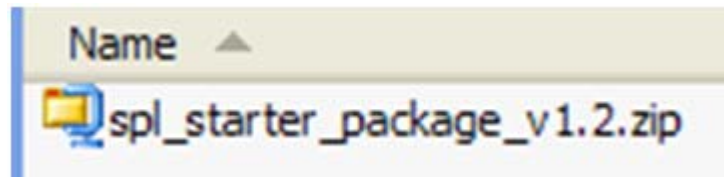
- Click the link to the SPL Starter Package
- Choose to “Save” the starter package.

Store SPL Starter Package



- Select computer location to save SPL Starter Package
- Place in a folder on computer

Unzipping the SPL Starter Package



- Unzip the SPL Starter Package by EXTRACTING to location
- Right-click with computer mouse to begin unzipping.
- DO NOT just open zip file containing this package

Open SPL Starter Package Folder



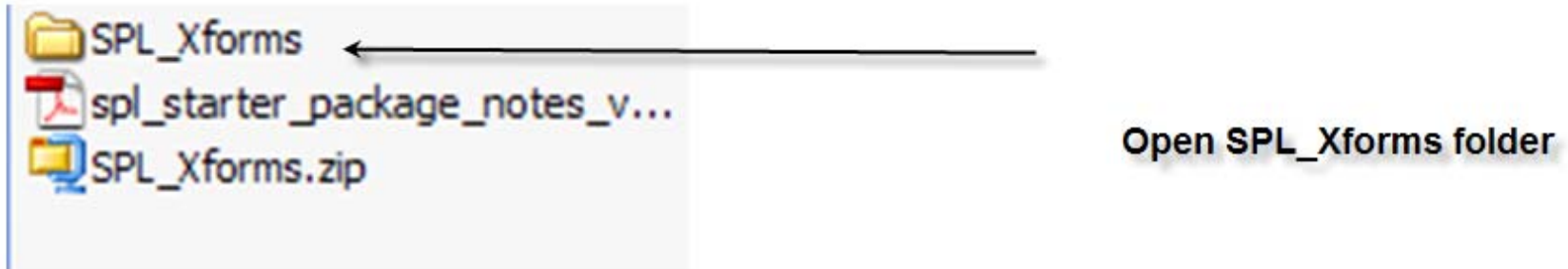
- After unzipping SPL Starter Package zip file, the SPL Starter Package folder should be available.

Read SPL Starter Package Notes



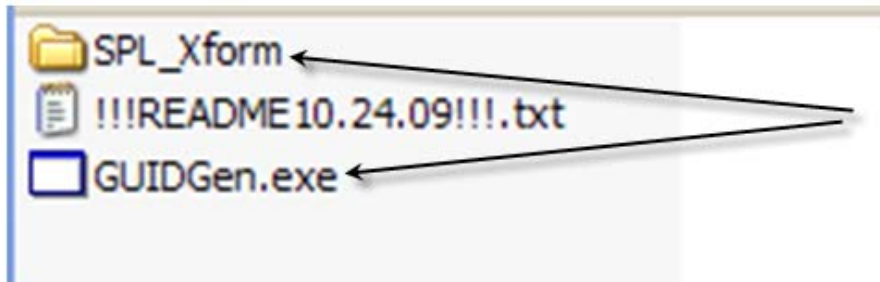
- Open PDF file to review SPL Starter Package Notes

Open SPL Xforms Folder



- After reading SPL Starter Package notes, open SPL_Xforms folder

Continue Accessing SPL Xforms



Open SPL_Xform folder
and
Click GUIDGen.exe file to open

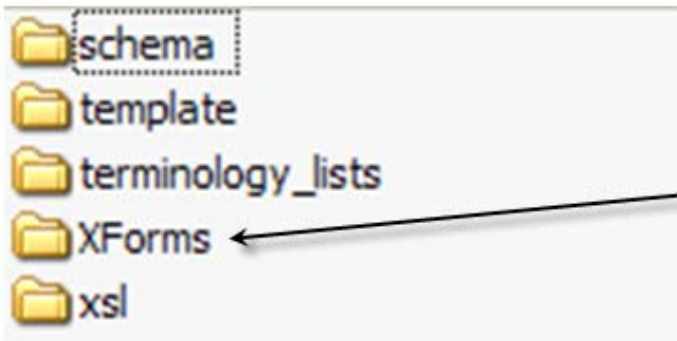
- Open another folder named SPL_Xform
- Double-click “GUIDGen.exe file to use at later time.
- If GUIDGen.exe is unaccessible, use online GUID generator by searching web for “online GUID generator”

Opening SPL Xforms Folder



- Open folder labeled “SPL”
- Ignore other folders

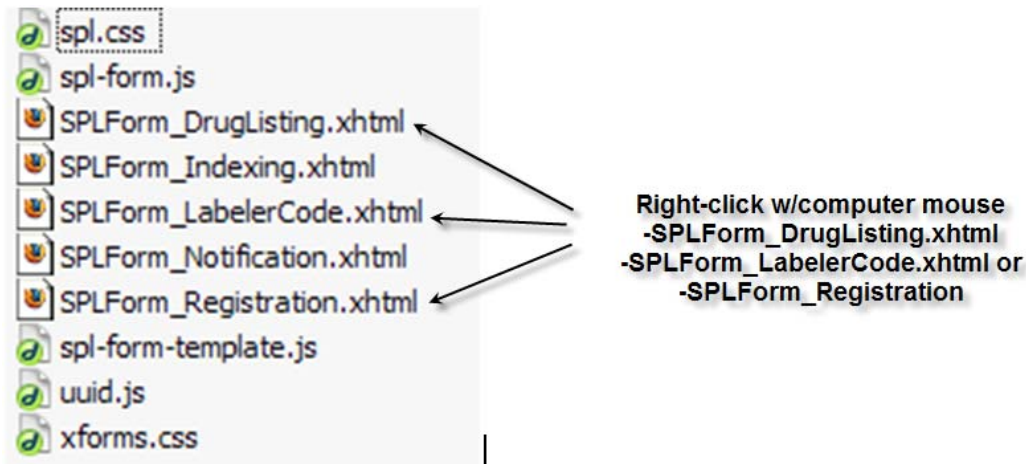
Opening Xforms Folder



Open "XForms" folder

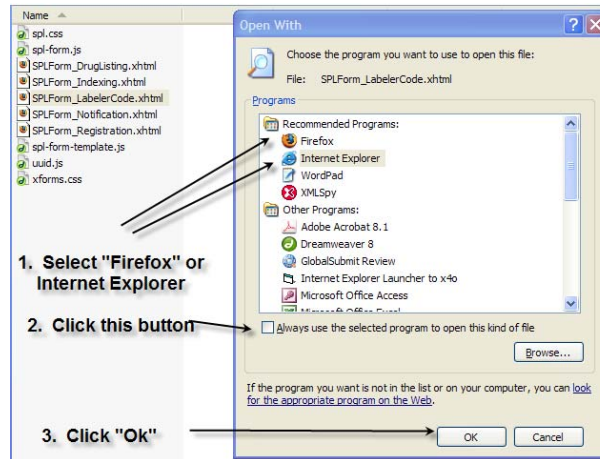
- Open the folder labeled “Xforms”
- Ignore other folders

Opening SPL Xforms for 1st Time



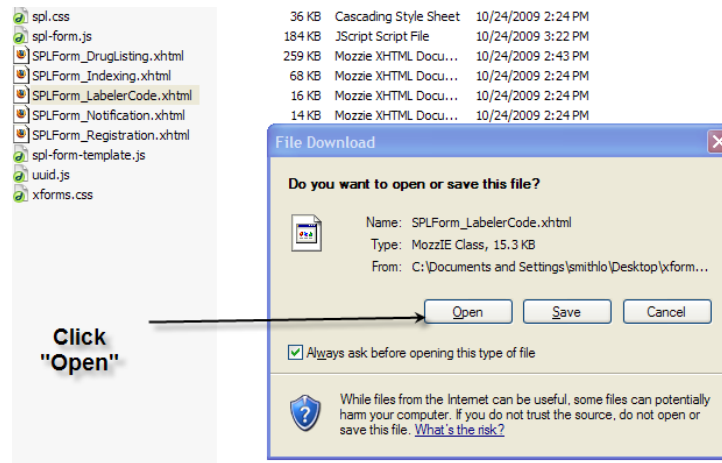
- To open the SPL Xforms for the first time
 - Right-click w/computer mouse **one** of these files:
 - SPLForm_DrugListing.xhtml
 - SPLForm_LabelerCode.xhtml
 - SPLForm_Registration.xhtml

Choose a Program



- After right-clicking
 - Choose "Open-with"
 - Select "Choose program" or equivalent
 - Choose "Internet Explorer" or "Firefox"
 - Check the box labeled "Always use the selected program to open this kind of file"
 - Select "Ok"
- These steps need only to be completed during first attempt at accessing Xforms. Subsequent instances of opening Xforms should only require clicking to open with computer mouse.

Opening the SPL Xforms



- Choose “Open” to begin opening SPL Xforms

Viewing SPL Xforms

The screenshot displays a web-based form titled "HL7 SPL - NDC Labeler Code Request v 1.00". At the top, there are buttons for "Open", "Save As", and "Save". Below these is a tabbed interface with "NDC Labeler Code Request" and "Preview" tabs. The form is organized into three main sections: "Document Information", "Labeler", and "Contact".

Document Information

Type of document	<input type="text"/>
ID	<input type="text"/>
Set ID	<input type="text"/>
Version Number	<input type="text"/>
Effective Time	<input type="text"/> example(YYYYMMDD)

Labeler

Name	<input type="text"/>
DUNS Number	<input type="text"/>

Below the Labeler section are two buttons: "Add NDC Labeler Code" and "Delete NDC Labeler Code".

Contact

Name	<input type="text"/>
Mailing Address	<input type="text"/>
City	<input type="text"/>
State	<input type="text"/>
Country	<input type="text"/>
Postal Code	<input type="text"/>
Telephone Number	<input type="text"/> tel:*
Email Address	<input type="text"/> mailto: example(mailto:xportal@globalsubmit.com)

- SPL Xforms should display
- Fields should be accessible for data entry
- If fields are inaccessible, then download Mozzie add-on again or contact spl@fda.hhs.gov

Need More Detailed Instructions?

- Use Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for Drug Establishment Registration and Drug Listing
- This document is located on the SPL Resources web page:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of 90 – 95% of technical errors in SPL documents.

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph explaining the council's role in coordinating data standards. At the bottom of the main content area is a link for 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)